

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

CLIFTON S. HARTWELL	:	
	:	
Plaintiff,	:	CIVIL ACTION NO.
	:	
vs.	:	
	:	
UNITED STATES OF AMERICA	:	
	:	
Defendant.	:	
	:	

COMPLAINT

Plaintiff, Clifton S. Hartwell ("Hartwell"), by and through his attorneys, James E. Beasley, Jr. and Heidi G. Villari, brings this Complaint in Civil Action against the United States of America for damages in the amount to guarantee a jury trial, and in support thereof alleges as follows:

PREAMBLE

It was Abraham Lincoln who first penned the credo of the U.S. Department of Veteran Affairs and its hospitals, as their mission is "to care for him who shall have borne the battle." This is a medical malpractice action against the United States of America by Plaintiff, Clifton S. Hartwell, Rank E-4, United States Army Veteran.

PARTIES

1. Plaintiff, Clifton S. Hartwell, is an adult individual and at all times material hereto resides at 17 Bellview Rd, Marysville, Pennsylvania 17053.
2. Defendant, United States of America (hereinafter "United States"), is the governmental entity that maintains the U.S. Department of Veteran Affairs, its divisions and subdivisions.

3. The U.S. Department of Veteran Affairs was established by Congress to administer the healthcare system for the Veterans of the United States, which includes health administration of the VA Healthcare System including the VA Pittsburgh Healthcare System where the alleged medical malpractice took place.

4. The VA Pittsburgh Healthcare System, (hereinafter "VA Pittsburgh") is a subdivision of the VA Healthcare System and is an agency of defendant, United States. Its facilities include psychiatric and pharmacy services, and is located at University Drive Campus, University Drive, Pittsburgh, Pennsylvania, 15210.

5. Defendant, United States, is responsible for the acts and/or omissions of its employees and is directly responsible for injuries sustained to Plaintiff; its individual Defendant physicians and its failed medication reconciliation and cross checking systems permitted a dangerous cocktail of Topiramate (Topamax) and Risperidone (Risperdal) to be prescribed without any warnings; this caused the Plaintiff to suffer grievous injuries due to improper medication administration and the failure to warn the Plaintiff of the possible injuries caused by the dangerous medication combination ordered by and approved for use by the USA.

6. Defendant, United States, by and through its agencies, VA Pittsburgh—University Drive Division and the pharmacies which approved the Plaintiff's prescriptions, hired, retained, contracted with, supervised, controlled and is responsible for physicians, pharmacists and other health care providers including its physicians, nurses, pharmacists, medical staff involved in the care and treatment of Clifton S. Hartwell at VA Pittsburgh.

7. The VA assigned Mr. Hartwell to its “beta team” of health care providers all of whom were acting within the course and scope of their employment of Defendant, United States. Defendant, United States, is responsible for the acts and/or omissions of its direct employees on the beta team.

8. Suman Ahuja, M.D., at all times material hereto, was a physician and/or medical care provider at the VA, and a member of the beta team when she negligently and carelessly treated Mr. Hartwell.

JURISDICTION AND VENUE

9. This Court has jurisdiction as the claims herein are brought against the Defendants pursuant to the Federal Tort Claims Act (28 U.S.C. §2671, *et seq.*) and 28 U.S.C. §1346(b)(1), for money damages as compensation for personal injuries caused by the Defendant's negligence.

10. Venue is proper within this district under 28 U.S.C. §1402(b) as the acts complained of occurred in the Western District of Pennsylvania.

NOTICE

11. Plaintiff incorporates by reference paragraphs 1 through 10 of this Complaint.

12. On or about November 20, 2013, Plaintiff, Clifton S. Hartwell, timely filed one (1) executed Standard Form 95 form with the Department of Veterans Affairs the Office of Regional Counsel, thereby timely making an administrative claim for damages and injuries consistent with the Federal Tort Claims Act, 28 U.S.C. §2671 *et seq.* (See Notice of Claim attached as Exhibit “A”).

13. On or about November 26, 2013, the Office of Regional Counsel for the Department of Veteran Affairs acknowledged receipt of the service of the claim and requested additional information. (See attached as Exhibit "B").

14. On or about January 27, 2014, Plaintiff further supplemented this submission with additional information and medical records sent to the Department of Veterans Affairs Office of Regional Counsel. (See attached as Exhibit "C"). Despite various communications by and between plaintiff's counsel and the Veteran Affairs of Regional Counsel, the parties have been unable to come to a resolution.

15. The six-month Federal Tort Claims Act period under 28 U.S.C. §2675 has expired with no response or final denial of Plaintiff's claim.

16. This Complaint is timely, pursuant to 28 U.S.C. §2401, as it has been filed within the time requirements set forth and Plaintiff has exhausted all necessary administrative remedies prior to bringing this action, thus vesting jurisdiction in this Court.

FACTS

17. Plaintiff incorporates by reference Paragraphs 1 through 17 of this Complaint.

18. Clifton S. Hartwell was born in 1974 and, as a child of the military, lived in various locations although most of his life has been spent in the Pennsylvania area. In 1991, Clifton S. Hartwell joined the United States Army. He was stationed in various places including but not limited to Fort Indiantown Gap, Pennsylvania; Fort Knox, Kentucky; Fort Sill, Oklahoma and deployed to Gernsheim, Germany. He served for

12 years. In 2003, Clifton S. Hartwell was honorably discharged from the United States Army. At the time of discharge, he was ranked E-4, specialist.

19. Clifton S. Hartwell served his country well but had succumbed to the occupational hazards of a veteran and at various times of his life had previously suffered from ETOH abuse, psychiatric conditions including bipolar disorder and major depression disorder. He was lithium-allergic and had bouts of homelessness. However, at all times material hereto, Mr. Hartwell had been in recovery and was living at the VA Domiciliary at the time he encountered Dr. Ahuja. His life was on the upswing and he was doing well.

20. He had been living in the Pittsburgh, Pennsylvania area so that he could be close to his eight (8) year old daughter. He was also working at the VA domiciliary, having administrative desk duties and also responsible for mowing the lawn.

21. On or about June 11, 2012, Mr. Hartwell was actively in treatment. In the process, he was treated at the VA Pittsburgh, by psychiatrist, Dr. Suman Ahuja. On the aforementioned date, Dr. Suman Ahuja negligently and carelessly prescribed a dangerous combination of psychiatric medications including Topiramate (Topamax) and Risperidone (Risperdal), and the VA permitted these medications to be dispensed even though of the great risk of side effects which ultimately injured Mr. Hartwell.

22. Topamax is typically used to treat seizures and has been approved worldwide for the treatment of various kinds of epilepsy and was currently being evaluated for its effects in various neurological and psychiatric disorders.

23. Risperdal is used to treat schizophrenia and symptoms of bipolar disorder. These two drugs, when combined, have a known deadly interaction - hyperthermia.

24. The pharmacy which received the prescription and approved this dangerous medication combination never warned Mr. Hartwell of the possibility of hyperthermia; neither did Dr. Ahuja or any other VA healthcare provider.

25. Mr. Hartwell had shown symptoms of bipolar disorder and his previous medications were known or should have been known to Suman Ahuja, M.D. prior to the prescription medication change at or about the June 11, 2012 visit.

26. Within one week of Mr. Hartwell's prescription change, and as the result of the medication change, on June 18, 2012, Mr. Hartwell, while mowing the lawn at the domiciliary, collapsed with "heatstroke." This collapse was directly and proximately caused by the prescription change made by Dr. Ahuja and permitted, without warning to be dispensed to him by the VA pharmacy; as such, Mr. Hartwell suffered catastrophic and permanent injuries as more detailed below for the months and years to follow, which are now ongoing.

27. On the day before his collapse, he was at a BBQ and was in a happy and healthy state.

28. At approximately 15:39 on June 18, 2012, following the collapse, a medic unit was dispatched. Mr. Hartwell was found lying on the ground unresponsive at the maintenance building at VA Aspinwall (HJ Heinz VA) Aspinwall, Pennsylvania. There were reports from the crew that he had been cutting the grass.

29. He was found with cold water bottles around him and in his armpit area that was placed by the VA medic crew. Mr. Hartwell had a reported axillary temperature of 108°F. He was tachycardic in the 160s, oxygen saturation was 87, blood sugar in the 140s.

30. He was emergently taken to UPMC Presbyterian-Emergency Department. In the trauma unit, he was unresponsive with emesis in his oropharynx. He was hot to touch and nonresponsive to verbal stimuli.

31. His lung sounds were decreased and diminished bilaterally. He had bounding femoral pulses. His abdomen was distended and intubation was necessary for airway protection. He was given etomidate and rocuronium. Once he had bag-valve ventilation to improve his oxygen saturation, he was orotracheally intubated under direct laryngoscopy. An oral gastric tube was also placed for gastric decompression.

32. Mr. Hartwell was given liters of cold saline along with a cooling blanket to try to bring his temperature down. He was placed on propofol for sedation. His lactate was elevated at 3 and his creatine level was increased to 1.7. He was hyponatremic with sodium in the high 120s.

33. He remained unresponsive as the UPMC Presbyterian physicians worked to cool his temperature to 100°F and rule out the differential for such extreme hyperthermia. Serotonin syndrome was ruled out and it was determined that Mr. Hartwell's heat stroke was NMS¹-related as a result of the daily drug interaction. The reaction was severe as Mr. Hartwell was acidotic, in acute respiratory failure, and had developed, among other things, acute stomach necrosis, acute liver failure, and acute renal failure.

34. Mr. Hartwell was admitted to the MICU as he continued to remain acidotic and hypotensive. He was placed on sodium bicarbonate drip and levophed. During the admission, he continued to suffer shock, and altered mental status, while his

¹ Neuroleptic malignant syndrome.

family members including his two sisters and ex-wife were bed side at various times. He also had a right femoral triple lumen CVC placed. A head CT scan was obtained which showed diffuse cerebral edema and his raised intracranial pressure was managed by mannitol infusion and hyperventilation, and found to be consistent with hepatic encephalopathy.

35. On the morning of June 19, 2012, his platelets had decreased from 138 to 37 and an INR had increased from 1.3 to 5. The patient was given 10 bags of cryoprecipitate and 4 units of fresh frozen plasma in anticipation of arterial catheter and IJ HD catheter placement but repeat INR was 2.9, so the procedures were not then done.

36. Mr. Hartwell's laboratory values continued to be highly abnormal; his transaminases began to rise precipitously by the morning of June 20, 2012. With time marching onward, his ALT increased from 79-to-125- to- 2566- to- 4578; his AST increased from 103- to- 160- to 3189- to- 4438; his T- bilirubin increased from 1.4-to- 1.9- to 3.2-to-4.5. His INR increased from 1.2-to-3.7-to-5.0-to-5.6-to-8.1-to-10.1. He was found to be in fulminant hepatic failure.

37. On June 21, 2012, Mr. Hartwell was placed on a liver transplant list.

38. A search of his room at the VA domiciliary revealed a pill bottle of Risperdal.

39. On June 21, 2012, Mr. Hartwell was transferred to the VA Pittsburgh where he would have a traumatic and difficult course over the following months due to the profound hyperthermia from the medications administered, without warning, by Dr. Ahuja and Defendant, United States. Mr. Hartwell remained in fulminant hepatic

failure, shock, gastrointestinal bleeding, required a total gastrectomy, a tracheostomy, contracted ventilator associated pneumonia, ARDS splenic abscess, PICC, TPN placed percutaneous drains of the abdomen and lung; and suffered abdominal wall defect. He required vacuum-assisted wound closure and wound care. He also developed bilateral pulmonary emboli. (See history and physical exam from Select Medical marked as Exhibit "D").

40. Throughout this difficult and long hospital course, Mr. Hartwell was severely malnourished and suffered total parenteral nutrition along with titrating doses of feedings via his jejunostomy tube.

41. Plaintiff had bouts of multi-drug resistant pseudomonas infection involving his drains and was treated with multiple courses of antibiotics concluding in a course of aminoglycosides. He was also treated for anti-staphylococcus infection. The patient was given vancomycin treatment for staphylococcus infection. He had also suffered ischemic necrosis of his digits upon presentation and by the time of discharge had dry gangrene involving four digits on his hands. He required amputations. He could not walk.

42. After the two months+ hospital stay at VA Pittsburgh, Mr. Hartwell was transferred to in-patient rehabilitation on August 13, 2012 to Select Specialty facility as he was trach-dependent and required weaning, occupational and physical therapies, and in need of wound care treatment. He was discharged on October 14, 2012 (nearly 4 months following his collapse) to home, where he remained on a feeding tube for approximately 12 additional months.

43. He had ROUX-Y procedure in June, 2013 to reconnect his esophagus to the jejunum at VA Pittsburgh and his treatment for his injuries as outlined in this Complaint is ongoing-to-date.

44. Defendant, United States, had a duty to provide reasonable, necessary and appropriate medical care to Mr. Hartwell that was consistent with the standard of care within the medical community. Defendant committed significant departures from the standard of care which are the direct and proximate cause of Mr. Hartwell's significant and plentiful injuries.

45. It was known or should have been known by the Defendant that Mr. Hartwell was at risk for a significant drug interaction and complicating hazard that would cause the severe hyperthermia leading to the conditions, multi-hospitalizations, surgical procedures, damages and losses that are outlined in this Complaint.

46. It is a fundamental proposition of medicine that whenever a patient such as Clifton S. Hartwell is medicated, the drug interactions be checked by the prescribing psychiatrist, a pharmacopsychiatrist, and the pharmacy prior to dispensation. This was not done. It is further fundamental that the Defendant was obliged to maintain an accurate accounting of the medications for their veteran patient Hartwell and be on the "look-out" for such dangerous effects of drugs so as to warn their veteran-patients.

47. The carelessness and negligence in prescribing and dispensing these combined medications that were contraindicated, without reference, without H&P, without warning and without monitoring Mr. Hartwell were substantial factors in bringing about Plaintiff's injuries and losses and increased the risk that Mr. Hartwell would suffer from the complications described in this Complaint.

48. The careless and negligent acts and omissions of the Defendant for its failure to implement and follow thru on administrative policies and procedures in the Defendant's failure to alert its physicians, pharmacies and veteran-patients of the potential psychotropic drug interaction increased the risk of harm to Mr. Hartwell and/or was the factual cause of his injuries and losses.

49. The injuries and losses suffered by the Plaintiff are the direct and proximate result of the negligence and carelessness of the Defendant and its agent acting individually or in concert and are not due to any act or failure to act on the part of the Plaintiff.

COUNT I

PLAINTIFF V. THE UNITED STATES OF AMERICA

50. Plaintiff incorporates by reference Paragraphs 1 through 50 of this Complaint.

51. The United States knew or should have known of the contraindication of the drug interaction between Topamax and Risperdal and thus, caused the severe hyperthermia which led to the aforementioned condition. The United States knew or should have known of the substantial risk for Mr. Hartwell's serious drug interaction yet failed to warn Mr. Hartwell, and failed to properly monitor and continue to monitor him during the first week of ingestion. Accordingly, the Defendant is responsible for the claims made in this lawsuit.

52. The negligence and carelessness of the Defendant, United States, acting directly and through its agents (actual ostensible or otherwise) servants and/or employees included the following:

- a. Vicarious liability for the negligence acts of its agents, servants and/or employees including Dr. Samun Ahuja;
- b. Failure to properly monitor Mr. Hartwell for a known dangerous complicating interactive hazard when the drugs Topamax and Risperdal are prescribed;
- c. Failure to ensure that psychotropic patients are not given a deadly combination of drugs so as to cause severe dangerous conditions such as severe hyperthermia;
- d. Failure to perform a complete history and examination in advance of prescribing and dispensing the deadly combination of drugs Topamax and/or Risperdal;
- e. Failure to adequately assess Mr. Hartwell and to recognize that he was not a candidate for the mixing of Topamax and Risperdal;
- f. Improperly administering medications known to have severe complications such as hyperthermia, necrosis, altered mental state, liver failure and the conditions developed by Mr. Hartwell during his complicated course;
- g. Failure to ensure Mr. Hartwell's medical safety following the administration of new medications;
- h. Negligently and carelessly utilizing unsafe medications in concert;
- i. Failure to warn Mr. Hartwell of the drug interactions when prescribing and dispensing Topamax and Risperdal;

- j. Without sound medical basis, providing Mr. Hartwell with a false sense of belief that he was in good health;
- k. Failure to warn and educate Mr. Hartwell regarding the severe and potentially fatal complications, including hyperthermia associated with the prescribed drug combination;
- l. Failure to interpret and assess the prescriptions for potential adverse reactions or side effects;
- m. Failure to exercise due care in the professional practice of psychiatry;
- n. Failure to properly and adequately treat and care for Mr. Hartwell;
- o. For other negligent acts of commission and omission that caused the catastrophic injuries to Mr. Hartwell;
- p. Negligently and carelessly exposing Mr. Hartwell to two drugs that were contraindicated without obtaining a proper consult, such as a pharmacopsychiatrist;
- q. Failure to review and/or perform a complete H&P before prescribing and dispensing Topemax and/or Respirdal in concert.

54. The negligence of the Defendant, as described herein, was the legal cause of the Plaintiff's injuries and described damages as described herein.

55. The negligence of the Defendant, as described herein, increased the risk of harm to Mr. Hartwell who suffered the injuries and damages as detailed in the within Complaint.

56. As a direct and proximate result of the negligence and carelessness of the Defendant, and as described herein, the Plaintiff suffered and the Defendant is liable to the Plaintiff for the within described injuries and damages.

57. As a direct and proximate result of the negligence and/or carelessness of the Defendant as described herein, Mr. Hartwell suffered the following injuries and damages:

- a. stomach necrosis; acute liver failure; bilateral pulmonary emboli; clotting; clots in all four limbs; respiratory failure leading to tracheostomy placement; traumatic brain injuries; diffuse cerebral edema and increased intracranial pressure; hepatic hyperthermia; coma; tachycardia; aspiration; neuroleptic malignant syndrome; extreme necrosis of fingers and toes; amputation of fingers; loss of function of extremities; conscious pain and suffering, both mental and physical during and subsequent to his hospitalizations; abdominal wall defect and open wounds; gastrectomy; tube feeding; central line placement; physical and occupational therapies, short term and long term memory loss, bowel and bladder incontinence, multiple surgeries, ROUX-Y procedure to connect esophagus to small bowel, balance issues, decreased/loss of partial vision, unable to climatize his body, unable to be outdoors during extreme weather, and an increase in sexual dysfunction; loss of abdominal wall musculature; abdominal pain; inability to eat; malnutrition; fatigue; loss of balance and core strength.

- b. loss of enjoyment of life's pleasures, multiple surgeries and future surgeries; loss of wages; loss of future earning capacity; past wages; decreased life expectancy; mental anguish and emotional distress;
- c. Embarrassment and humiliation.

58. As a result of the aforesaid injuries caused by Defendant, Plaintiff sustained the following damages:

- a. Plaintiff has been and may be required to incur various expenses in connection with the providing of medical and surgical attention, hospitalization, medical supplies, surgical appliances, medicines and attending services;
- b. Plaintiff's general health, strength and vitality have been impaired; permanent damage to multiple organs; years of chronic pain and/or discomfort; other severe and serious injuries.

COUNT II

PLAINTIFF V. THE UNITED STATES OF AMERICA

59. Plaintiff incorporates by reference Paragraphs 1 through 58 of this Complaint.

60. The United States knew or should have known of the contraindication of the drug interaction between Topamax and Risperdal and thus, caused the severe hyperthermia which led to the aforementioned condition. The hospital, dispensing pharmacy and Dr. Ahuja knew or should have known of the potential for Mr. Hartwell's serious drug interaction yet failed to warn Mr. Hartwell, properly monitor and continue

to monitor him during the first week of ingestion. Accordingly, the Defendant is responsible for the claims made in this lawsuit.

61. The negligence and carelessness of the Defendant, United States, acting directly included the following:

- a. Failure to develop, administer implement and/or train hospital personnel on medication interactions involving psychotropic drugs including but not limited to Topamax and Risperdal;
- b. Failure to properly communicate within the hospital systems concerning the deadly drug combination and issuing precautionary warnings to physicians and its pharmacies that would otherwise be in a position to prescribe psychotropic and epileptic medications;
- c. Failure to provide proper oversight to the healthcare team including Dr. Samun Ahuja to ensure that Mr. Hartwell would receive timely monitoring and treatment to reverse the drug interaction and/or catch it early enough to have rendered Mr. Hartwell Safe from harm;
- d. Failure to have proper policies, procedures and protocols in place to ensure communication is made from the psychiatrist to the pharmacy so that all drugs used and administered in the treatment of the patient is known;
- e. Failure to implement the proper policies, procedures and protocol to ensure patients are warned and counseled by the United States

and its physicians related to medications and its contraindications included but not limited to Topamax and Risperdal;

- f. Failure to develop and/or administer the appropriate policies and/or procedures to ensure the necessary and vital call-back of patients who are prescribed medications that are contraindicated for significant drug interactions and/or hazards;
- g. Failure to maintain medication reconciliation records on all veteran-patients including Mr. Hartwell so as to avoid causing severe drug interaction;
- h. Failure to properly select competent, trained and supervised health care providers who are capable of meeting the requisite standard(s) of care in the practices of psychiatry, pharmacopsychiatry, pharmacology, neurology and endocrinology and to ensure proper consult with these disciplines prior to ordering a dangerous mix of medications as was done here;
- i. Failure to maintain a proper drug interaction warning system prior to dispensation of the medications;
- j. Failure to develop, administer, implement a training program and/or train hospital personnel on medication interactions involving psychotropic drugs including but not limited to Topamax and Risperdal;

- k. Failure to implement proper monitoring policies, procedures and protocols for a known dangerous complicating and interactive hazard when the drug Topamax and Risperdal are prescribed;
- l. Failure to maintain a unified records system so that all drugs prescribed to patient is known to the current treating physician.

62. The negligence of the Defendant, as described herein, was a legal cause of the Plaintiff's injuries and damages as described herein.

63. The negligence of the Defendant, as described herein, increased the risk of harm to Mr. Hartwell who suffered the injuries and damages as detailed in the within Complaint.

64. As a direct and proximate result of the negligence and carelessness of the Defendant, and as described herein, the Plaintiff suffered and the Defendant is liable to the Plaintiff for the within described injuries and damages.

65. As a direct and proximate result of the negligence and/or carelessness of the Defendant as described herein, Mr. Hartwell suffered the following injuries and damages:

- a. stomach necrosis; acute liver failure; bilateral pulmonary emboli; clotting; clots in all four limbs; respiratory failure leading to tracheostomy placement; traumatic brain injuries; diffuse cerebral edema and increased intracranial pressure; hyperthermia; coma; tachycardia; aspiration; neuroleptic malignant syndrome; extreme necrosis of fingers and toes; amputation of fingers; loss of function of extremities; conscious pain and suffering, both mental and

physical during and subsequent to his hospitalizations; abdominal wall defect and open wounds; gastrectomy; tube feeding; central line placement; physical and occupational therapies, short term and long term memory loss, bowel and bladder incontinence, multiple surgeries, ROUX-Y procedure to connect esophagus to small bowel, balance issues, decreased/loss of partial vision, unable to climatize his body, unable to be outdoors during extreme weather, and an increase in sexual dysfunction; loss of abdominal wall musculature; abdominal pain; inability to eat; malnutrition; fatigue; loss of balance and core strength.

- b. loss of enjoyment of life's pleasures, multiple surgeries and future surgeries; loss of wages; loss of future earning capacity; past wages; decreased life expectancy; mental anguish and emotional distress;
- c. Embarrassment and humiliation.


66. As a result of the aforesaid injuries caused by Defendant, Plaintiff sustained the following damages:

- a. Plaintiff has been and may be required to incur various expenses in connection with the providing of medical and surgical attention, hospitalization, medical supplies, surgical appliances, medicines and attending services;
- b. Plaintiff's general health, strength and vitality have been impaired; permanent damage to multiple organs; years of chronic pain and/or discomfort; other severe and serious injuries.

WHEREFORE, Plaintiff, Clifton S. Hartwell, demands judgment against Defendant, The United States of America, exclusive of costs and such other remedies as this Honorable Court deems just and proper.

THE BEASLEY FIRM, LLC

By:



JAMES E. BEASLEY, JR., M.D., LL.M.
PA Attorney L.D. No. 83282
The Beasley Firm, LLC
1125 Walnut Street
Philadelphia, Pennsylvania 19107
215.592.1000
215.592.8360 (telefax)
jim.beasley@beasleyfirm.com
Attorney for Plaintiff